The Medtronic Mosaic Bioprosthesis (305C, 305U, and 310C) is Magnetic Resonance Imaging (MRI) conditional. Non-clinical testing and modeling has demonstrated that the device is acceptable for patients undergoing MRI examinations at 3.0 Tesla or less and is labeled MR Conditional under ASTM F2503 - Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

ASTM F2503 is the active standard regarding MR acceptability; the device was evaluated and classified according to these guidelines. It is the responsibility of the user to establish appropriate safety and health practices prior to use.

**The device can be scanned safely under the following conditions:**
- Static magnetic field of 1.5 Tesla and 3.0 Tesla
- Spatial gradient field of 2500 gauss/cm or less
- Normal or First Level Controlled Mode with a maximum whole body specific absorption rate (SAR) of 4.0 W/kg for 15 minutes of scanning

**RF Heating**

**1.5 Tesla**
Based on nonclinical testing and modeling, the device was calculated to produce a temperature rise of less than 2.2°C at a maximum whole body averaged SAR of 4.0 W/kg for 15 minutes of MR scanning in a GE Signa 64 MHz (1.5 T) whole body transmit coil.

**3.0 Tesla**
Based on nonclinical testing and modeling, the device was calculated to produce a temperature rise of less than 2.2°C at a maximum whole body averaged SAR of 4.0 W/kg for 15 minutes of MR scanning in a 128 MHz (3.0 T) GE Signa HDx 3.0 T MR system.

**Deflection and Torsion**

**1.5 Tesla and 3.0 Tesla**
The device will not move or migrate when exposed to MR scanning immediately after implantation. MRI at 1.5 Tesla and 3.0 Tesla may be performed immediately following the implantation of the device.

**Image Artifact**
MR image quality may be compromised if the area of interest is in the same area, or relatively close to the position of the device. It may be necessary to optimize MR imaging parameters for the presence of this implant. When tested at 3.0 Tesla, the image artifact extended less than 20 mm beyond the device for spin echo and gradient echo sequences.

The presence of other implants or medical circumstances of the patient may require lower limits on some or all of the above parameters.

If you have additional questions, or if we can be of assistance to you in any way, do not hesitate to contact us at your convenience.

Medtronic CardioVascular LifeLine
8200 Coral Sea Street N.E.
Mounds View, MN 55112
Phone: (763) 526-7890 Toll Free: (877) 526-7890
Fax: (763) 526-7888 Email: Rs.cstechsupport@medtronic.com
### Materials
- Acetal homopolymer covered with polyester fabric
- Radiopaque Eyelets: Haynes® alloy no. 25

### Third Generation Tissue Technologies
- AOA® (alpha amino oleic acid) tissue treatment
- Physiologic Fixation™ process

### Specifications

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<th>Valve Size (Stent O.D.) (A)</th>
<th>Orifice Diameter (Stent I.D.) (B)</th>
<th>Suture Ring Diameter (C)</th>
<th>Valve Height (D)</th>
<th>Aortic Protrusion (E)</th>
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Equivalents to annulus diameter

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AOA® tissue treatment
Stent post markers allow radiographic visualization
Physiologic Fixation™ process allows valves to maintain natural leaflet structure and natural root geometry
Scalloped suture ring enables Supra-X™ placement (aortic only) to maximize blood flow
Deflecting stent posts ease insertion into annulus
Polyester sewing ring with felt insert provides strength with low suture drag
Soft, compliant sewing ring securely seals against annulus
Green suture marker aids in orientation of valve

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### Materials
- Acetal homopolymer covered with polyester fabric
- Radiopaque Eyelets: Haynes® alloy no. 25
Catalog # 763966
1 pliant handle

Handle to be used with Mosaic Obturators.

References:
6. Data on file, Medtronic, Inc.